Supreme Court, U.S.
FILED
NOV 14 1996
CLERK

No. 96-575

IN THE

Supreme Court of the United States

October Term, 1996

BRACCO DIAGNOSTICS INC. and
BRACCO INTERNATIONAL B.V.,
Petitioners,

v.

DAVID A. KESSLER, M.D.,
COMMISSIONER OF FOOD AND DRUGS, and
BRUCE A. LEHMAN,
ASSISTANT SECRETARY OF COMMERCE and
COMMISSIONER OF PATENTS AND TRADEMARKS,
Respondents,

and

GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR RESPONDENT GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION IN OPPOSITION

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12 pp

COUNTERSTATEMENT OF THE QUESTION

Did the Court of Appeals correctly reject Petitioner's demand under the Uruguay Round Agreements Act ("URAA") for a second extension of the term of a drug patent previously extended under 35 U.S.C. § 156, which bars such second extensions, where Petitioner's patent would not have been in force on the effective date of URAA but for its first § 156 extension?

RULE 29.6 STATEMENT

Respondent Generic Pharmaceutical Industry Association is a New York not-for-profit corporation. It has no parent companies, subsidiaries or affiliates.

The following firms are members, associate members and affiliate members of the association: A.L. Pharma Inc., Apothecon, Barr Laboratories, Clonmel Healthcare Ltd., Copley Pharmaceutical, Inc., Creighton Products Corporation, Endo Laboratories L.L.C., ESI Lederle Generics, Geneva Pharmaceuticals, Inc., Global Pharmaceutical Corporation, Zenith Goldline, Hoechst Celanese Corporation, Lemmon Company, Perrigo Company, Rosemont Pharmaceutical Corporation, Hoechst Marion Roussel, Inc., Schein Pharmaceutical, Inc., Warner Chilcott Laboratories, Warrick Pharmaceuticals, ACIC Limited, Agvar Chemicals, Inc., Aesgen, Inc., Darby Group Companies, Inc., GYMA Laboratories of America, HMS Sales & Marketing, Inc., Interchem Corporation, KRKA, Lek USA, Inc., PharmaKinetics Laboratories, Phoenix International Life Sciences, PLIVA USA INC., Ranbaxy Pharmaceuticals, Inc., Ren-Pharm International, Ltd., Century Financial Services, Inc., Newport Data Associates, Inc., ScinoPharm International, Ltd., CCL Label, Intercall, Inc., and MIM Promark Holdings.

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Merck & Co. v. Kessler, 80 F.3d 1543 (Fed.Cir. 1996) . . . . . *passim*

Statutes and Treaties

35 U.S.C. § 154 . . . . . *passim*

35 U.S.C. § 156 . . . . . *passim*

Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984) . . . . . *passim*

Uruguay Round Agreements Act of 1994 ("URAA"), Pub. L. 103-465, 108 Stat. 4809 (1994) . . . . . *passim*

Agreement on Trade-Related Aspect of Intellectual Property Rights ("TRIPs"), H.R. Doc. No. 316, 103rd Cong., 2d Sess. 1621 (1994) 1, 5-6

BRIEF OF RESPONDENT GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION IN OPPOSITION

Respondent Generic Pharmaceutical Industry Association ("GPIA") respectfully opposes the joint petition of Bracco Diagnostics Inc. and Bracco International B.V. (collectively, "Petitioner" or "Bracco") for a writ of certiorari to the United States Court of Appeals for the Federal Circuit.

COUNTERSTATEMENT OF THE CASE

GPIA is dissatisfied with Petitioner's statement of the case in the following respects:

1. This case does not involve "international obligations" of the United States under the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPs"), contrary to the suggestion at pages 2-3 of the Petition. The only TRIPs provisions even remotely bearing upon this case are the articles requiring that all patents in force on the effective date of the TRIPs Agreement be given a life of not less than 20 years from the date of first application for a patent. For Petitioner's patent, that 20-year period ended on November 24, 1995. The TRIPs standard was more than satisfied in this case, since Petitioner's patent remained in effect until January 4, 1996.

2. Petitioner erroneously states at page 4 that the Food and Drug Administration ("FDA") granted it a two-year patent extension under the Hatch-Waxman Act. In fact, all

such extensions, including the one that was received for the Bracco patent, are granted by the Commissioner of Patents and Trademarks pursuant to an application made by the patent holder to the Patent and Trademark Office ("PTO") and in accordance with the standards and procedures of 35 U.S.C. § 156. FDA is not authorized to issue patents or extensions of patent terms.

3. In accordance with 35 U.S.C. § 156(e)(1), the two-year Hatch-Waxman Act extension granted to Petitioner in December 1986 became "part of the original patent" which had been issued on January 4, 1977. This extension period began to run on January 4, 1994, when Petitioner's original 17-year patent term would have otherwise expired. Thus over 17 months of the 24 months of extension which were granted to Petitioner pursuant to the Hatch-Waxman Act were used up by June 8, 1995, when the URAA became effective. Petitioner's patent was still in force on that date only by reason of its receipt and use of that Hatch-Waxman extension.

4. The case below dealt with 4 other patents similarly situated to Petitioner's — one belonging to Organon Inc., and three belonging to Syntex (U.S.A.) Inc. Organon filed a petition for certiorari in this Court (No. 96-562), but its claim, as far as the petition indicates, has plainly become moot: even under Organon's own view of the merits, the term of its patent would have expired on November 6, 1996, and Organon has suggested no circumstances that have created a live controversy. Syntex has not asked this Court to review the Federal Circuit's ruling with respect to its three affected patents. Moreover, although there are believed to be a

significant number of other patents similarly situated[1] — and similarly restricted to their single pre-URAA Hatch-Waxman extension by the terms of the underlying PTO and FDA positions, and now by the Court of Appeals — none of those patentees saw fit to bring an action or to intervene in the proceedings below. Petitioner is the only claimant of continuing patent rights that were foreclosed by the decision below who still seeks to pursue this issue.

5. The number of drug patents affected is both fixed and finite. Only patents which were granted Hatch-Waxman extensions before the June 8, 1995 effective date of URAA, and which remained in effect through that date solely through use of those extensions, are potentially affected — and only a portion of those are actually affected by the decision below. While important in dollar terms, the issues raised by Petitioner are not of broad legal significance.

6. The Bracco patent, having exhausted its Hatch-Waxman extension period, expired on January 4, 1996 under the judgment of the Federal Circuit. Organon's request to the Federal Circuit for a stay pending the filing of its petition for certiorari was denied, and no stay was sought in this Court. Thus Petitioner is trying to revive a dead patent. In fact, after the District Court's final order pursuant to the Federal Circuit's remand, the FDA on November 6, 1996 granted approval of an Abbreviated New Drug Application, ANDA No. 74-629, for a generic version of the drug covered by Bracco's now-expired patent.

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[1]See Brief for Federal Respondents in Opposition in Nos. 96-562 and 96-575 at p.9.

REASONS FOR DENYING THE WRIT

Petitioner fails to demonstrate grounds for this Court to review the portions of the decision of the Federal Circuit to which it objects. The Petition does not even contend that the Federal Circuit has decided an important federal question in a manner that conflicts with another circuit or with any decision of this court, or which should be settled by this Court, or which has in any way departed from the accepted and usual course of judicial proceedings so as to call for an exercise of this Court's supervisory power.

On the contrary, as to Bracco, the Federal Circuit made the only possible decision reasonably reconciling the provisions of two separate statutes potentially affecting Bracco's patent. Indeed, as set forth in GPIA's simultaneously filed conditional cross-petition, Respondent believes that the Federal Circuit was, if anything, overly generous to drug patentees as a group, in allowing them to cut and paste any previously granted Hatch-Waxman extensions from 17-years-from-issuance terms to the newly established 20-years-from-application terms. Although Petitioner is understandably disappointed by the fact that the appellate court having exclusive appellate jurisdiction over patent cases rejected its position, the Petition raises no general federal legal issue which merits this Court's review.

Certainly, as to this Petitioner — the ***only*** affected patentee claiming an unexpired patent who has made any effort to pursue this case — the decision of the Federal Circuit is both correct and fair. Petitioner received the full benefit of its two year Hatch-Waxman extension to January 4, 1996, without which — notwithstanding the URAA — the patent would have forever expired on January 4, 1994. And

Petitioner also received all that any patentee is guaranteed under the URAA: an expiration date which was at least 20 years from the date of first application, which in Petitioner's case would have been November 24, 1995.

Section 156(a) requires that the grant of a Hatch-Waxman extension be accomplished "in accordance with" that section of the law; but § 156 not only provides no basis or procedure for the relief Petitioner seeks, it affirmatively precludes that relief. Clearly, granting Petitioner a second 2-year Hatch-Waxman extension at the end of its newly authorized URAA 20-year term, after it had used up 17 months of its first Hatch-Waxman extension just to remain in force on the URAA effective date, would have (1) violated the explicit prohibition of § 156(a)(2) against multiple Hatch-Waxman extensions, (2) given Petitioner a total of 41 months of Hatch-Waxman extensions, when the limit applicable to Petitioner was 24 months under § 156(g)(6)(C), and (3) given Petitioner an illogical and unfair windfall which serves none of the purposes of either Hatch-Waxman or URAA, at the expense of the American public.

Petitioner thus has no reasonable basis for complaint about the decision below, and this Court has no reason to review it.

Pursuant to Rule 15.2, in addition to the matters set forth above, Respondent also draws the Court's attention to the following perceived misstatements of fact or law in the petition:

a. Petitioner wrongly but repeatedly insinuates that there is some issue of discrimination in this case, either under the TRIPs Agreement or the URAA, which implements TRIPs.

See, e.g., Petition at pp. 6, 7, 8. However, as the Petition itself reveals (p. 7), the discrimination targeted by TRIPs was "discrimination as to the place of invention, the field of technology and whether products are imported or locally produced" (quoting from Article 27:1 of TRIPs). Petitioner makes no argument that any such discrimination arises out of the Federal Circuit's decision in this case, and there is no basis whatever for making such a claim.

b. The Petition asserts at page 11 that "under the URAA the term of all patents in force on June 8, 1995 is the *greater* of" 17 years from grant of a patent plus the Hatch-Waxman extension or 20 years from application plus the Hatch-Waxman extension. The URAA contains no such provision. In fact, read literally, the only option which the URAA gives an eligible patentee is ***either*** 17 years from date of issue ***or*** 20 years from date of application — the statute actually contains no explicit provision for any Hatch-Waxman extensions. Of course, that literal reading of URAA would make no sense because it would truncate an existing Hatch-Waxman extension, such as Petitioner's, which extended an original 17 year patent to a date more than 20 years from date of application. But both PTO and the Federal Circuit avoided that result as to Petitioners by concluding that Congress did not intend to supersede Hatch-Waxman *sub silentio*, and that the pre-existing "extended" patent term separately established under § 156 remains available even if it is longer than the 20 year option.

CONCLUSION

The petition for a writ of certiorari to the Federal Circuit should be denied.

Respectfully submitted,

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November 14, 1996